HORMONAL TREATMENT IN TRANSGENDER INDIVIDUALS

WPATH (World Professional Association for Transgender Health)
(Serious) Adverse Event Report

Definitions

1. (S)AE A (serious) adverse event (SAE) is any new untoward medical occurrence in a transgender individual on hormonal treatment (e.g. venous thromboembolism, lactotroph adenoma, breast cancer, prostate cancer, ovarian cancer, lipid disorder, cardiovascular disease, cerebrovascular disease, diabetes mellitus, liver disease, Hepatitis infection, HIV infection, depression, ……).

2. Relatedness The criterion applied is a determination of whether there is a reasonable possibility that the event may have been related to the hormonal treatment. Note that a "reasonable possibility" does not include cases where there is only a remote or unlikely possibility that the SAE may have been caused by the treatment.

3. Seriousness An AE that meets one or more of the following criteria/outcomes is classified as serious:

- Death
- Life-threatening (i.e., immediate risk of death)
- In-patient hospitalization or prolongation of existing hospitalization
- Persistent or significant disability/incapacity

Important AEs that may not result in death, be life threatening, or require hospitalization may be considered serious when, based on medical judgement, they may jeopardize the patient or subject, or may require medical or surgical intervention to prevent one of the outcomes listed above.

Serious also includes any other AE that the physician or other health professional judges to be serious or which is defined as serious by the regulatory agency in the country in which the AE occurred.

Please fax or e-mail the following complete 3 pages to ……

Fax: 0032 9 240 38 97

E-mail: endocrinology@uzgent.be

CASE REPORT FORM centre (name + city) .....

Year - month - day patient initials + date of birth (e.g.: PVByymmdd)

Adverse Event Report date |_|_|_|_|_|_|_|_| |_|_|_|_|_|_|_|_|_|_|_|_|

Serious Adverse Event (SAE) (disease, if diagnosed, or symptoms)

..... Onset Year - month - day

..... date |_|_|_|_|_|_|_|_|

Outcome

DATE

Year - month - day

☐ Recovered
☐ Recovered with sequelae
☐ Not recovered
Chronic ☐ No
☐ Yes

|_|_|_|_|_|_|_|_|

☐ Recovering
☐ Death - - - - - - - - - - - - - -
☐ Unknown

Year - month - day

|_|_|_|_|_|_|_|_|

Is there a reasonable possibility that the SAE is related to hormonal treatment?

☐ No
☐ Yes

Further information (concerning relevant medical history, differential diagnosis of the event, sequelae, treatment of SAE etc.)

.....
.....
.....
.....
.....
.....
.....
.....

Action taken with hormonal treatment

☐ none ☐ drug withdrawn
☐ dose reduced ☐ dose delayed
☐ dose increased ☐ unknown

Event abated after use stopped or dose reduced?

☐ No ☐ Yes ☐ Not applicable ☐ Unknown

Did event reappear after reintroduction?

☐ No ☐ Yes ☐ Not applicable ☐ Unknown

	No	Yes
Has the SAE resulted in		
- death	☐	☐
- in-patient hospitalization or prolongation of existing hospitalization	☐	☐
- persistent or significant disability/incapacity	☐	☐
Is the SAE		
- life-threatening (i.e., immediate risk of death)	☐	☐
- any other AE that the physician judges to be serious or that is defined as serious by the regulatory agency in the country in which the SAE occurred	☐	☐

.....
Signature of Reporter .....

CASE REPORT FORM centre ……..

Year - month - day patient initials + date of birth (e.g.: PVByymmdd)

Adverse Event Report date ⌊⌊⌊⌊⌊⌊⌊⌊ ⌊⌊⌊⌊⌊⌊⌊⌊

Biological Sex ☐ male ☐ female

Relevant medical history

Date

	Start year - month - day	Stop year - month - day
Sex reassignment surgery?	⌊⌊⌊⌊⌊⌊⌊⌊	⌊⌊⌊⌊⌊⌊⌊⌊
……	⌊⌊⌊⌊⌊⌊⌊⌊	⌊⌊⌊⌊⌊⌊⌊⌊
……	⌊⌊⌊⌊⌊⌊⌊⌊	⌊⌊⌊⌊⌊⌊⌊⌊

Relevant laboratory data/tests

Component	Dosage	Unit	Date of specimen year - month - day
……	⌊⌊⌊⌊⌊	……	⌊⌊⌊⌊⌊⌊⌊⌊
……	⌊⌊⌊⌊⌊	……	⌊⌊⌊⌊⌊⌊⌊⌊
……	⌊⌊⌊⌊⌊	……	⌊⌊⌊⌊⌊⌊⌊⌊
……	⌊⌊⌊⌊⌊	……	⌊⌊⌊⌊⌊⌊⌊⌊

Hormonal therapy treatment (+ MOA*)

Date year - month - day

1) ……..	Treatment start	⌊⌊⌊⌊⌊⌊⌊⌊
	Last administration	⌊⌊⌊⌊⌊⌊⌊⌊
	Dose at SAE onset	⌊⌊.⌊⌊ ☐ mg/day
2) ……..	Treatment start	⌊⌊⌊⌊⌊⌊⌊⌊
	Last administration	⌊⌊⌊⌊⌊⌊⌊⌊
	Dose at SAE onset	⌊⌊.⌊⌊ ☐ mg/day
3) ……..	Treatment start	⌊⌊⌊⌊⌊⌊⌊⌊
	Last administration	⌊⌊⌊⌊⌊⌊⌊⌊
	Dose at SAE onset	⌊⌊.⌊⌊ ☐ mg/day

* mode of administration 1: oral, 2: transdermal, 3: intramuscular, 4: other

Relevant concomitant medication

Drug name	Dose	Unit	Frequency	Route	Date year - month - day
……	⌊⌊⌊⌊⌊	……	……	……	⌊⌊⌊⌊⌊⌊⌊⌊ Start
					⌊⌊⌊⌊⌊⌊⌊⌊ Stop
……	⌊⌊⌊⌊⌊	……	……	……	⌊⌊⌊⌊⌊⌊⌊⌊ Start
					⌊⌊⌊⌊⌊⌊⌊⌊ Stop
……	⌊⌊⌊⌊⌊	……	……	……	⌊⌊⌊⌊⌊⌊⌊⌊ Start
					⌊⌊⌊⌊⌊⌊⌊⌊ Stop

In case of death

Cause of death……

Autopsy ☐ No ☐ Yes If Yes , please attach copy of report, if available

CASE REPORT FORM centre ……..

Year - month - day patient initials + date of birth (e.g.: PVByymmdd)

Adverse Event Report date

Might the SAE be related to any of the following?

Underlying disease	☐ No	☐ Yes	If Yes, please specify ……
Concomitant drug therapy	☐ No	☐ Yes	……..
Known interactions	☐ No	☐ Yes	……..
Other factors	☐ No	☐ Yes	……..

Reporter name ……

Address ……

……

……

SAE Awareness date
year - month - day

Country ……

Telephone ……

Telefax ……

E-mail ……

☐ Physician ☐ Other health professional

If other, please specify ……

How many transgender individuals on hormonal treatment are seen on a yearly basis at your centre?

Biological Sex ☐ male

☐ female